

§ 1308.22

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based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(d) The Administrator may at any time revoke any exclusion granted pursuant to section 201(g) of the Act (21 U.S.C. 811(g)) by following the procedures set forth in paragraph (c) of this section for handling an application for

an exclusion which has been accepted for filing.

[38 FR 8254, Mar. 30, 1973, as amended at 70 FR 74657, Dec. 16, 2005; 75 FR 10678, Mar. 9, 2010]

§ 1308.22 Excluded substances.

The following nonnarcotic substances which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 201(g) (1) of the Act (21 U.S.C. 811(g) (1)):

EXCLUDED NONNARCOTIC PRODUCTS

| Company | Trade name | NDC code | Form | Controlled substance | (mg or mg/ml) |
|------------------------------|---|------------|------|---------------------------------------|---------------|
| Bioline Laboratories | Theophed | 00719–1945 | TB | Phenobarbital | 8.00 |
| Classic Pharmaceuticals LLC. | Nasal Decongestant Inhaler/Vapor Inhaler. | | IN | Levmetamfetamine (l-Desoxyephedrine). | 50.00 |
| Goldline Laboratories | Guiafled Elixir | 00182–1377 | EL | Phenobarbital | 4.00 |
| Goldline Laboratories | Tedrigen Tablets | 00182–0134 | TB | Phenobarbital | 8.00 |
| Hawthorne Products Inc ... | Choate's Leg Freeze | | LQ | Chloral hydrate | 246.67 |
| Parke-Davis & Co | Tedral | 00071–0230 | TB | Phenobarbital | 8.00 |
| Parke-Davis & Co | Tedral Elixir | 00071–0242 | EX | Phenobarbital | 40.00 |
| Parke-Davis & Co | Tedral S.A. | 00071–0231 | TB | Phenobarbital | 8.00 |
| Parke-Davis & Co | Tedral Suspension | 00071–0237 | SU | Phenobarbital | 80.00 |
| Parmed Pharmacy | Asma-Ese | 00349–2018 | TB | Phenobarbital | 8.10 |
| Rondex Labs | Azma-Aids | 00367–3153 | TB | Phenobarbital | 8.00 |
| Smith Kline Consumer | Benzedrex | 49692–0928 | IN | Propylhexedrine | 250.00 |
| Sterling Drug, Inc | Bronkolixir | 00057–1004 | EL | Phenobarbital | 0.80 |
| Sterling Drug, Inc | Bronkotabs | 00057–1005 | TB | Phenobarbital | 8.00 |
| Vicks Chemical Co | Vicks Inhaler | 23900–0010 | IN | l-Desoxyephedrine | 113.00 |
| White Hall Labs | Primatene (P-tablets) | 00573–2940 | TB | Phenobarbital | 8.00 |

[38 FR 8255, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 41 FR 16553, Apr. 20, 1976; 41 FR 53477, Dec. 7, 1976; 46 FR 51603, Oct. 21, 1981; 47 FR 45867, Oct. 14, 1982; 54 FR 2100, Jan. 19, 1989; 55 FR 12162, Mar. 30, 1990; 62 FR 13968, Mar. 24, 1997; 74 FR 44283, Aug. 28, 2009]

EXEMPT CHEMICAL PREPARATIONS

§ 1308.23 Exemption of certain chemical preparations; application.

(a) The Administrator may, by regulation, exempt from the application of all or any part of the Act any chemical preparation or mixture containing one or more controlled substances listed in any schedule, which preparation or mixture is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal, if the preparation or mixture either:

(1) Contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any sig-

nificant potential for abuse (the type of packaging and the history of abuse of the same or similar preparations may be considered in determining the potential for abuse of the preparation or mixture); or

(2) Contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse. If the preparation or mixture contains a narcotic controlled substance, the preparation or mixture must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have